**RE: SPECIAL 510(K): DEVICE MODIFICATION FOR THE WILSON-COOK MECHANICAL LITHOTRIPTOR**

K011178

PG. 1 OF 2

## I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY - 4 2001

**Submitted By:**
Wilson-Cook Medical Inc.
4900 Bethania Station Road
& 5951 Grassy Creek Boulevard
Winston-Salem, NC 27105

**Device Description:**
The Wilson-Cook Modified Mechanical Lithotriptor is used in conjunction with a side-viewing endoscope and a Soehendra Lithotriptor Handle to mechanically crush stones in the biliary duct when other methods of endoscopic removal have failed. This device is supplied non-sterile and intended for single use only.

| | |
|---|---|
| **Trade Name:** | Wilson-Cook Mechanical Lithotriptor |
| **Common/Usual Name:** | Mechanical Lithotriptor |
| **Classification Name/Code:** | Lithotriptror, Biliary Mechanical, GU, 78 LQC |
| **Classification:** | FDA has classified similar devices as Class II, as per 21 CFR § 876.4500. This device falls within the purview of the Gastroenterology and Urology Device Panel. |
| **Performance Standards:** | To the best of our knowledge, performance standards for this device do not exist. |
| **Intended Use:** | Used in conjunction with a side-viewing endoscope and a Soehendra Lithotriptor Handle to mechanically crush stones in the biliary duct when other methods of endoscopic removal have failed. |

**Predicate Device:**

| PREDICATE DEVICE | MANUFACTURER | DOCUMENT CONTROL NUMBER |
|---|---|---|
| Wilson-Cook Mechanical Lithotriptor | Wilson-Cook Medical | K902170 |
| Microvasive MonoLith Mechanical Lithotripter | Boston Scientific | K943191 |

**Substantial Equivalence:**
The Wilson-Cook Modified Mechanical Lithotriptor is substantially equivalent to the referenced predicate devices with respect to design, materials of construction and intended use.

## I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

| DEVICE CHARACTERISTIC | Wilson-Cook Modified Mechanical Lithotriptor [Subject of Special 510(k)] | Wilson-Cook Mechanical Lithotriptor (K902170) |
|---|---|---|
| Intended Use | Used in conjunction with a side-viewing endoscope and a Soehendra Lithotriptor Handle to mechanically crush stones in the biliary duct when other methods of endoscopic removal have failed. | Used to mechanically crush stones in the biliary duct when other methods of endoscopic removal have failed. |
| Sterility | Non-sterile, Disposable | Non-sterile, Reusable |

**Biocompatibility:**

Reasonable assurance of biocompatibility for the patient-contacting materials has been established through a history of use in similar patient-contacting medical devices and as applicable biocompatibility test results.

**Design Control/Risk Analysis/Design Verification:**

Design Control, Risk Analysis, Design Verification activities for the subject of this special 510(k) have been conducted in accordance with all applicable internal procedures. The design control process employed is inclusive of the elements as stipulated by 21 CFR Part 820.30, as applicable to the project. The risk analysis performed identified the risks relative to the performance requirements, as specified by our internal procedure for Risk Analysis. The failure mode, effect of failure, severity, potential cause, rate of occurrence, design control element/production controls to eliminate, the potential to detect and our recommended actions were also documented. During Design Verification, dimensional and functional testing to ensure the performance and design integrity of this product line were conducted. All results obtained during our Design Verification met our predetermined acceptance criteria for this product line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2001

Ms. Margaret J. Posner
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K011178
Wilson-Cook Thru-the-Scope Mechanical
Lithotriptor
Dated: April 12, 2001
Received: April 17, 2001
Regulatory Class: II
21 CFR §876.4500/Procode: 78 LQC

Dear Ms. Posner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

**510(k) Number (if known):** K011178

**Device Name:** Wilson-Cook Thru-the-Scope Mechanical Lithotriptor

**Indications for Use:**

Used in conjunction with a side-viewing endoscope and a Soehendra Lithotriptor Handle to mechanically crush stones in the biliary duct when other methods of endoscopic removal have failed.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE, IF NEEDED)

---

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011178